REMARKS

Claims 1-114 are pending, with claims 8-9, 17-19, 44-45, 51, 60-61, 67-81, 89-90, 97-98, 101, 106, and 108-112 being withdrawn without prejudice. Applicants note that of the independent claims, Examiner has only identified claim 1 as being generic. (Official Action, p. 3). Applicants respectfully submit independent claim 113 is generic as well. Of the non-withdrawn claims, independent claims 1, 38, 58, 82, 95, 103, 113, and 114 are amended. Of the withdrawn claims, independent claims 67 and 108 are amended. The non-withdrawn claims have been rejected under 35 U.S.C. § 103(a) on the basis of Alden et al-2005/0101979 ("Alden") in view of Hagen et al-6,348,043 ("Hagen") (and in the case of some claims, in further view of Simpson et al-5,002,066 ("Simpson")). While Applicants do not agree with the rejections, each of the non-withdrawn independent claims 1, 38, 58, 82, 95, 103, 113, and 114 have been amended in a similar manner to more clearly define around these references.

Applicants' invention is directed to a reservoir which is advantageously used as part of a closed blood sampling system. A closed blood sampling system generally includes tubing in fluid communication with the vasculature of a patient and allows blood samples to be taken therefrom via a sample site disposed in the tubing. The closed blood sampling system may further provide a convenient manner to monitor the patient's blood pressure. In this regard, a pressure-measuring device is coupled to the tubing and the tubing filled with saline so that the pressure in the tubing corresponds to the patient's blood pressure. When a blood sample is to be taken, the volume of the chamber of the reservoir is to be increased to cause fluid downstream of the reservoir to be pulled away from the patient and into the chamber of the reservoir. That process

causes blood to flow from the patient into the tubing. The fluid drawn into the reservoir enters into the chamber through the exit or downstream port of the reservoir. A sufficient amount of fluid (e.g., saline and possibly some blood) is pulled into the chamber such that whole, undiluted blood is in the sample site. An access device, such as a needle or a blunt cannula, is used to access the sample site to collect a whole blood sample. Once the blood sample is taken, the chamber is to be reduced in volume to, in effect, push the remaining blood in the tubing back toward and into the patient. To accomplish that, the volume of the reservoir is reduced which causes fluid in the chamber to exit back out through the same exit port for return toward the patient. Accordingly, it is an important feature of the present invention that the exit port be in bidirectional fluid communication with the chamber so that fluid flows into the chamber through the exit port such as to facilitate taking a blood sample, and fluid flows out of the chamber through the same exit port after the blood sample is taken to restore the system (irrespective of whether fluid flows into or out of the inlet or upstream port).

Each of the non-withdrawn independent claims has been amended to recite the bidirectional fluid communication aspect of the exit port of the reservoir. Alden, the primary reference relied upon by Examiner, does not have such a bidirectional fluid communication feature nor can it. In this regard, Alden's reservoir includes flow control elements so as to control the direction of blood flow toward and away from the reservoir via two separate ports. More specifically, Alden's reservoir is specifically designed to provide blood aspiration from a source (i.e., the finger of a diabetic patient) and then to transport the blood to a second remote location. Paragraph 25 of Alden, to which the

Examiner specifically recites in the Office Action as the basis of his rejections, makes this point clear:

> The diaphragm 310 may be used essentially as a pump to facilitate transfer of the blood to reach all areas required. Such required areas might be simple sample storage areas further downstream for assaying or for exposing the blood to a chemical sensor or other testing means. Delivery of the blood may be to sites within the sample acquisition module or to sites outside the sample acquisition module, i.e., a separate analysis device. In an alternate embodiment, a chemical sensor or other testing means is located within the sample acquisition module, and the blood is delivered to the chemical sensor or other testing means via a blood transfer channel in fluid communication with the sample reservoir.

(Alden, ¶ 25).

To permit the reservoir of Alden to aspirate a blood sample from a source and then transport the blood to a remote location, the reservoir includes a first check valve (312) at the entrance (302) to the chamber (300) and a second check valve (314) at the vent (306). As is well known, check valves are unidirectional flow devices that, in the case of Alden, allow the reservoir to operate for its intended purpose of aspirating a blood sample in through one port and then expelling it through another port for transport to a remote location. In this regard, the first check valve (312) allows blood to flow into the chamber (300) from the inlet channel (304) during expansion of the chamber (300) (caused by low pressure on the back side of the diaphragm (310)), but prevents blood from flowing back through the check valve (312) during contraction of the chamber (300) (caused by high pressure on the back side of the diaphragm (310)). In a similar manner, the second check valve (314) prevents blood flow into the chamber (300) from exit channel (316) during expansion of the chamber (300), but allows blood to flow out of chamber (300) during contraction of the chamber (300). In short, due to the check valves, any blood in the exit channel (316) is prevented from entering the chamber (300)

during expansion of the chamber (300), and blood in the chamber (300) is prevented from flowing into the inlet channel (304) during contraction of the chamber (300) so that a net transport of blood from the source and toward the remote location is effectuated.

Accordingly, the reservoir of Alden has fluid flow into the reservoir through one port and fluid flow out of the reservoir through another port, but does not (and would fail if it were modified to) allow for fluid flow into and out of the reservoir via the same port. This is in sharp contrast to that recited in the present, non-withdrawn independent claims wherein the reservoir can pull fluid from a source (e.g., the circulatory system of a patient) and return fluid back toward that same source through the same port of the reservoir. Moreover, Hagen and Simpson fail to cure the deficiencies in Alden. Even assuming for sake of argument that one of these references disclosed the bidirectional feature, one of ordinary skill in the art would not modify the reservoir of Alden to incorporate such a feature because it would result in a device that would not operate for its intended purpose. In particular, if fluid were to be able to exit out of the same port designed to collect the sample, then Alden would not be able to transport the sample to a remote location, which is its intended purpose. Modifying the reservoir so that the fluid is returned to the source from whence it was drawn (e.g., the body of the patient) would destroy the intended use of Alden's reservoir. Consequently, one of ordinary skill in the art would not be motivated to make such a modification. Thus for at least the foregoing reason, Applicants submit that the non-withdrawn independent claims, and therefore the claims which depend therefrom, are allowable.

Furthermore, because generic claims 1 and 113 are allowable, Applicants respectfully request that the Examiner bring back the withdrawn claims previously

restricted out of the case. Some of the withdrawn claims depend from non-withdrawn allowable independent claims and are therefore allowable for the reasons provided above. The remaining withdrawn claims are either independent withdrawn claims or depend therefrom. In particular, withdrawn independent claims 67 and 108 have been amended similar to the non-withdrawn independent claims so as to recite the bidirectional fluid communication aspect discussed above. Accordingly, upon bringing these independent claims back into the case, these claims, as well as those that depend therefrom, are submitted to be allowable as well.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the rejections have been overcome and the case is now in condition for allowance. Accordingly, a formal Notice of Allowance is solicited at the earliest possible time.

If, for any reason, the foregoing does not place this case in condition for allowance, or if any questions remain, Examiner is respectfully requested to telephone undersigned attorney in an effort to promptly resolve same.

No fee is believed due for this paper other than that for a two-month extension. If any other fee is due, please take this as authorization to charge same to our Deposit Account 23-3000.

Respectfully submitted,
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